



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration

555 Winderley Place

Suite 200

Orlando, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-11

November 18, 1998

Walter T. Bell, President
A.P. Bell Fish Company
4600 124th St. West
Cortez, FL 34215

Dear Mr. Bell:

On September 4 and 8, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 4600 124th Street West, Cortez, FL. The investigator documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the seafood products processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

Failure to control the potential ciguatera hazard that is reasonably likely to occur with the grouper received and distributed by your facility, in that no monitoring records are maintained to document that the fish were not harvested from an area with a history of ciguatera. [123.6(b) & (c)(7)]

Failure to list in the HACCP plan or control the potential environmental chemical contaminant and pesticide hazards that are reasonably likely to occur with the mullet received and distributed by your facility. [123.6(b) & (c)(1)]

You should prepare separate plans for grouper and mullet, since a written HACCP plan, specific to each kind of fish and fishery product processed, is required unless the safety hazards are identical. [123.6(b)(2)]

In addition, your firm fails to exclude pests from the food plant [123.11(b)(8)] in that two dogs were noted in the receiving area near the end of the conveyor belt where the fish are packed into boxes on wet ice and near the office in the processing area, and your sanitation monitoring records lack the date and time of each sanitation check and the signature and/or initials of the individual performing the sanitation check. [21 CFR 123.9(2) & (3)]

It is unclear why your firm selected evisceration as a critical control point for the prevention of toxin formation. The toxins associated with grouper, ciguatoxin, and mullet environmental contaminants do not increase with temperature abuse, nor can they be controlled during evisceration. As noted in this Warning Letter, these hazards are best controlled by making sure that incoming fish have not been caught in a contaminated area. Chapters 6 and 9 of the Fish & Fishery Products Hazards & Controls Guide provide more detailed information on the control of these hazards.

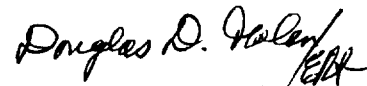
The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any of the seafood products processed at your facility until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,

A handwritten signature in dark ink, appearing to read "Douglas D. Tolen", with a stylized flourish at the end.

Douglas D. Tolen
Director, Florida District